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EXAMINER	
ROZANSKI, MICHAEL T	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,155	FLAHERTY ET AL.	
	Examiner	Art Unit	
	MICHAEL ROZANSKI	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11-14,17-19,29-34 and 36-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11-14,17-19,29-34 and 36-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

-In claim 1, line 6, "said first blood vessel" lacks antecedent basis.

-In claim 1, it is unclear how the imaging transducer operates in regard to the catheter device, as there is no evident relationship between the two.

Claim Objections

Claim 1 is objected to because of the following informalities: In line 9, the word "the" should be inserted before the term "target". Appropriate correction is required.

For broad categorization purposes, in the two lines of rejection presented below the **Yock/Yock et al** -based rejections pertain to angioplasty devices meaning devices acting on intravascular stenoses via a tissue penetrator and/or work tool such as a balloon and have a *generally forward tool port along the catheter axis for a tool confined within the vasculature,* whereas the **Crowley/Seward et al** rejections pertain to angioplasty as well as extravascular operation such as myocardial ablation or revascularizing

channelization and are cited in relation to *generally lateral tool ports with respect to the catheter axis for tools adapted to extend beyond the vasculature.* (See Seward et al col. 9 lines 12-20, col. 10 lines 22-39 and 56-65 statement of scope).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(b,e) as being anticipated by Yock et al (US5724977), which teaches a guide catheter 10 advanceable into a blood vessel and a stenotic tissue penetrator 39 (angioplasty catheter of Fig. 8) as well as a rotating imaging transducer fixed to an imaging catheter 38 such that the imaging transducer and the marker (24 or 26) cooperate to enable the operator to rotationally orient the catheter until the penetrator path is indicated to be aimed at, for example a stenotic branch vessel soas to assure that when the penetrator is advanced it will properly ingress this desired vessel.

With respect to claim 2, Yock et al includes instruction to use a rotational imaging device col. 5 lines 45-57 or a phased array col. 7 lines 16-23.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Crowley (US5588432) wherein Crowley et al teaches a catheter device including a tissue penetrator 396, 314 respectively associated with balloon needle egress and electrode ablation tip needle egress as depicted in Figs. 21, 21a and 29, 29a respectively, in the context of a combined diagnostic imaging and general intervention catheter which has a rotating ultrasonic imaging transducer within a catheter and longitudinally translatable therewithin and capable of viewing the intervention site. Two modes of marker are suggested for this system:radioopaque markers 410, 412 as per col. 17 lines 64-65 which serve to define the long axis of the catheter and its general location, and alternatively acoustic marking in the form of PVDF deposition over the ablating electrodes or over generalized portions of the catheter which serve as markings detectable by a separate transesophageal ultrasound probe to serve in a position sensing function to create a wire frame or anatomic image onto display 376 as detailed in cols. 23-24

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Yock et al in view of Yock (US5000185). The Yock et al discussion of an imaging catheter 38 includes a col. 5 reference to that shown in the '185 patent's face figure as aforementioned. While it would be prudent in Yock et al to first image access entry to the lesion site via 38 before operating in-situ imaging of the progress of site atherectomy using transducer 51 fixedly mounted to bell cutter 29 (meaning that), it would have been obvious in view of the latter to use imaging transducer 51 to view the progress of atherectomy which entails further tool advancement and stenotic lumen penetration such that it may be reasonably said that marker 24 or 26 as well as transducer 51 cooperate to orient and indicate the penetrator path.

A re-statement of the aforementioned '102/103 rejections with respect to claim 1 is that under the anticipatory interpretation the Examiner is proposing that Yock et al alone is sufficient to anticipate *an imaging transducer fixedly mounted to an imaging catheter* to cooperate with a marker to assist in interventional tool positioning in the context of the overall catheter system combination whereas Yock et al in view of Yock would render obvious *an imaging transducer fixedly mounted to an interventional catheter* to cooperate with a positioning marker, the whole or cutter part of which can be construed as a tissue penetrator.

Dependent claim 2 is rejected analogous to the above, with the distinction that under the latter interpretation the phased array called for in the Yock et al col. 7 passage

is assumed to be transferrable to the treatment catheter 39 since the overall discussion therein is of Yock-genre catheters.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yock et al as applied to claim 3 above, alone or further in view of Yock, further in view of Proudian et al (US4917097). It would have been obvious in view of the latter col. 7 line 17 - col. 10 line 41 to provide a full 360 degree annular array for the phased array called for in Yock et al since Proudian et al while practicing balloon angioplasty as opposed to penetrative interventions recognizes that the annular or full 360 degree array view is useful to characterize atheromatous lesions which may occupy significant sectors about the radius of the therapy catheter.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yock et al alone or further in view of Yock as applied to claim 1 above, and further in view of Sieben (US5445155) or Scribner et al (US5054092).

In the case of Sieben, this patent is directed to a thin profile intracoronary imaging catheter as per col. 7 lines 1-58 (or to a sheathless, guidewire imager as per col. 29 lines 45-57 of no further interest). In the catheter or 'sheathed (40)' embodiment, Figs. 7a -7b as discussed within the overall SHEATH discussion col. 18 line 63 - col. 19 line 56, both static torque drag and dynamic whiplash effects acting on the rotatable transducer drive cable are compensated for by the use of longitudinal *acoustic* indexing markers *interiorly* disposed at nominal 45 degree increments about the hollow lumen of 40, all of which if incorporated into either into the wall of guide catheter 10 or of imaging 38 or therapy 39 catheters of the Yock et al or Yock et al v Yock devices would serve to define

a cage structure aligned with the interventional path in order to *internally reference the imager to its catheter* thereby assisting in the overall orienting process. Insofar as Yock et al's guide catheter 10 must be orientationally marked for the user to manipulate to access the delivery site and also the interventional and imaging catheters 38, 39 must be orientationally marked, in the former case if the imager is a long axis phased array, in the latter case in order to align with an assymmetric artery wall lesion , it would have been obvious in view of Sieben to modify reflector 26 of guide catheter 10 to be a cage-like structure or to place index marks like 80,92 on an imaging or interventional catheter 38,39 for the motivational reasons mentioned.

In the case of Scribner et al 160, 86,98,100, it would have been obvious to incorporate *fluoroscopic* markers onto the *exterior* of a catheter sheath, that is, exteriorly about the hollow interior, *in order to position-reference the catheter to it's environment at large,* in the device of Yock et al or Yock et al v Yock since the Scribner et al device is similar to the 5,000,185 patent in design and purpose. (Scribner et al also contains internal acoustic index reference 47 which is analogous to the Sieben index marks.)

Claims 1-2, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley in view of McGee et al (US5,752,518) or Yock et al. It would have been obvious in view of McGee et al that since electrodes 31, 32 are intrinsically by nature passive markers, see col. 13 lines 52-55, the electrode 316 would be visible on the CT scan of col. 24 line 23 soas to mark the exit port of the tissue penetrator. Also, since the said electrode is intrinsically and by nature visible to ultrasound col. 21 lines 44-46 of

Crowley it is again a marker specific for the lateral penetrator exit port albeit not a rotationally orienting one in either the CT or UTS case. In the case of Yock et al 24, since an aperture perimeter is also intrinsically viewable from within a catheter, it is argued in light thereof that the needle egress portals of Crowley Figs. 21 and 29 would be visible as a 'mark' of sorts when the rotating imaging transducer is slid along the catheter axis soas to be directly opposed to the aperture, whereupon a 'mark' that is both local to and orientationally defining of the tissue penetrator port is had.

(Hence the reason for subdividing the Crowley et al-based rejection is that while the identified markers of Crowley are omni-directional (viewable from all directions hence non-orienting about the catheter axis) and non-specifically located with respect to the tool port, and the identified marker 26 of Yock et al and 60, etc. of Scribner et al are longitudinally orienting, and the principal rejection is along these lines, the vagaries of claim 1 necessitate that the Examiner present art as well for the case of markers which are both proximal to the tool port and/or orienting with respect to the port aperture (McGee, 24 of Yock et al, which see).)

With respect to claim 6, the protruding needles shown in Crowley must be resilient since they cannot serve their function flaccid.

Claims 3-4, 7, 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley as applied to claim 2 above, alone or further in view of McGee et al or Yock et al, and further in view of Seward et al (US5713363).

With respect to claim 11, it would have been obvious in view of Yock et al 24 to view the tool port as a marker since the sliding transducer is intended to be brought within this field of view to monitor the tool working.

Claims 12, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 11 above, and further in view of Scribner et al which teaches that catheter orienting markings may be made part of the overall orienting marker system in order to rotationally orient a therapeutic catheter.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley as applied to claim 1 above, and further in view of Sieben or Scribner et al. It would have been obvious in view of the latter to either internally acoustically mark-reference the transducer with respect to the catheter to assist in overall orienting of the side-port therapy of Figs. 21,21a,29,29a in the case of the former, or to externally fluoroscopically mark-reference the catheter with respect to the environment in the case of the latter.

Claims 13, 29-31, 34, 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley in view of Seward et al, as representing lateral port penetrator tool catheters with ultrasound imaging wherein it would have been obvious in view of Seward et al to provide a circumferential phased array for the imaging transducer in order to omni-directionally view a worksite such that at least one such transducer would beam the penetrator path, Crowley otherwise describing color display highlighting due to acoustic marking transducers as aforementioned.

With respect to claims 42, 43 Seward et al includes ablation electrodes for penetrating the myocardium with a flow of electrical energy.

With respect to claims 44-45, the relationship between the orienting markers and the imaging display is discussed supra in relation to Crowley.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley in view of Seward as applied to claim 13 above, and further in view of Yock et al insofar as the latter would teach use of a laterally orienting marker24, 26 to determine catheter orientation.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley in view of Seward et al as applied to claim 13 above, and further in view of Crowley (US5715825) insofar as the latter literally mentions guidewire embodiments with neckdowns 152, 92 as pertains to this family of imaging/interventioanl catheter devices.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley in view of Seward et al as applied to claim 31 above, and further in view of Scribner et al in that the latter would teach use of hash marks to locate rotational orientation of the catheter.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 11-14, 29-34, and 36-45 (which were previously rejected under double patenting) have been considered but are moot in view of the new ground(s) of rejection. Currently, 1-7, 11-14, 17-19, 29-34, and 36-45 are rejected, wherein claims additional claims 7 and 17-18 are rejected because originally elected claims 11 and 19 depend from said additional claims, respectively. Examiner also advises applicant to put the correct claim status identifier for the claims not examined and previously withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR